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The House Committee on Regulated Industries offers the following substitute to SB 178:

A BILL TO BE ENTITLED AN ACT

1 To amend Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to

- 2 grounds for suspension, revocation, or refusal to grant licenses by the State Board of
- 3 Pharmacy, so as to provide that the use of the mails or other common carriers to sell,
- 4 distribute, and deliver a prescription drug directly to a patient under certain circumstances
- 5 shall not be considered grounds for sanctioning the license of a pharmacist; to provide for
- 6 related matters; to repeal conflicting laws; and for other purposes.

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BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 **SECTION 1.** 9 Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to grounds for 10 suspension, revocation, or refusal to grant licenses by the State Board of Pharmacy, is amended by revising paragraph (11) of subsection (a) as follows: 11 12 "(11) Regularly employing the mails or other common carriers to sell, distribute, and 13 deliver a drug which requires a prescription directly to a patient; provided, however, that 14 this provision shall not prohibit the use of the mails or other common carriers to sell, 15 distribute, and deliver a prescription drug directly to: (A) A patient or directly to a patient's guardian or caregiver or a physician or physician 16 17 acting as the patient's agent for whom the prescription drug was prescribed if: (i) Such prescription drugs are prescribed for complex chronic, terminal, or rare 18 19 conditions; 20 (ii) Such prescription drugs require special administration, comprehensive patient 21 training, or the provision of supplies and medical devices or have unique patient 22 compliance and safety monitoring requirements; 23 (iii) Due to the prescription drug's high monetary cost, short shelf life, special 24 manufacturer specified packaging and shipping requirements or instructions which 25 require temperature sensitive storage and handling, limited availability or distribution, 26 or other factors, the drugs are not generally carried in the regular inventories of retail

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pharmacies such that the drugs could be immediately dispensed to multiple retail

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walk-in patients: 2 3 (iv) Such prescription drug has an annual retail value to the patient of more than 4 \$6,000.00; 5 (v) The patient receiving the prescription drug consents to the delivery of the prescription drug via expedited overnight common carrier and designates the specialty 6 7 pharmacy to receive the prescription drug on his or her behalf; (vi) The specialty pharmacy utilizes, as appropriate and in accordance with standards 8 9 of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time 10 temperature strips, insulated packaging, or a combination of these; and 11 (vii) The specialty pharmacy establishes and notifies the enrollee of its policies and 12 procedures to address instances in which medications do not arrive in a timely manner 13 or in which they have been compromised during shipment and to assure that the 14 15 pharmacy replaces or makes provisions to replace such drugs; or (B) An an institution or to sell, distribute, or deliver prescription drug refills, upon his 16 or her request, to an enrollee in a health benefits plan of a group model health 17 maintenance organization or its affiliates by a pharmacy which is operated by that same 18 group model health maintenance organization and licensed under Code Section 19 26-4-110. Any pharmacy using the mails or other common carriers to dispense 20 21 prescriptions pursuant to this paragraph shall comply with the following conditions: 22 The pharmacy shall provide an electronic, telephonic, or written (A)(i) 23 communications mechanism which reasonably determines whether the medications 24 distributed by the mails or other common carriers have been received by the enrollee 25 and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to 26 27 offer counseling to the enrollee as authorized by and in accordance with his or her 28 obligations under Code Section 26-4-85, unless the enrollee refuses such consultation 29 or counseling pursuant to subsection (e) of such Code section. In addition, the 30 enrollee shall receive information indicating what he or she should do if the integrity 31 of the packaging or medication has been compromised during shipment; 32 (B)(ii) In accordance with clinical and professional standards, the State Board of 33 Pharmacy shall promulgate a list of medications which may not be delivered by the 34 mails or other common carriers. However, until such list is promulgated, the group 35 model health maintenance organization shall not deliver by use of the mails or other 36 common carriers Class II controlled substance medications, medications which 37 require refrigeration, chemotherapy medications deemed by the federal

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1 Environmental Protection Agency as dangerous, medications in suppository form, and 2 other medications which, in the professional opinion of the dispensing pharmacist, 3 may be clinically compromised by distribution through the mail or other common 4 carriers; 5 (C)(iii) The pharmacy shall utilize, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration 6 7 and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and 8 9 (D)(iv) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner 10 11 or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs. 12 For purposes of subparagraph (B) of this paragraph, the term 'group model health 13 maintenance organization' means a health maintenance organization that has an 14 exclusive contract with a medical group practice to provide or arrange for the provision 15 of substantially all physician services to enrollees in health benefits plans of the health 16 17 maintenance organization;"

18 SECTION 2.

19 All laws and parts of laws in conflict with this Act are repealed.